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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/970,043	10/02/2001	Jae Hyong Byon	KBPCO.001APC	8684

20995 7590 05/20/2003

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EXAMINER

MCINTOSH III, TRAVISS C

ART UNIT	PAPER NUMBER
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1623

10

DATE MAILED: 05/20/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

File Copy

Office Action Summary	Application N .	Applicant(s)	
	09/970,043	BYON ET AL.	
	Examiner	Art Unit	
	Traviss C McIntosh	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 February 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9, 12-17, 19-24, 26, 29-34, 36-48, 50-52, 55, 56 and 59-62 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

- 5) ☒ Claim(s) 41-48, 50-52 and 55 is/are allowed.
- 6) ☒ Claim(s) 1-9, 12-17, 19-24, 26, 29-34, 36-40, 56 and 59-62 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>9</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

The Amendment filed February 20, 2003 has been received, entered into the record, and carefully considered. The following information provided in the amendment affects the instant application by:

Claims 1, 3, 7-9, 12, 13, 24, 29-34, 36-41, 48, 50-52, 56, and 59-61 have been amended.

Claims 10, 11, 18, 25, 27-28, 35, 49, 53-54, and 57-58 have been canceled.

~~New claim 62 has been added.~~

Remarks drawn to rejections of Office Action mailed August 13, 2002 include:

Foreign Priority: acknowledgement is made of applicants claim to priority to

International Application No. PCT/KR01/00139 under 35 U.S.C. § 120 or 365(c).

112 1st paragraph rejections have been overcome by applicants' amendments which removed "prevention" and have been withdrawn.

112 2nd paragraph rejections have been overcome by applicants amendments which added the units of measure where needed.

103(a) rejections which have been obviated by applicants' amendments and comments.

An action on the merits of claims 1-9, 12-17, 19-24, 26, 29-34, 36-48, 50-52, 55-56, and 59-62 is contained herein below.

The text of those sections of Title 35, US Code which are not included in this action can be found in a prior Office action.

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Claim Objections

Claim 39 is objected to because of the following informalities: the claim has the repetitive term “wherein wherein” which appears to be a typographical error. Appropriate correction is required.

Claim 61 is objected to because of the following informalities: the claim has a misspelling of “polygluronate” which the examiner thinks should be “polyguluronate”. Appropriate correction is required.

Claim Rejections - 35 USC § 112

Claims 2, 3, 12, 33-34, 36-40, 56, and 59-62 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 2 and 3 are indefinite wherein the recitation in a dependent claim of the source of a starting material to be used in a method from which said claim depends, wherein the "source of said starting agent" does not result in a patentably distinguishable methodological and manipulative difference in how said starting material's source impacts the method from which it depends, renders the claim(s) in which it occurs and which depend therefrom indefinite for failing to distinctly articulate how such a recitation further limits the method from which said claim(s) depend.

Claim 12 is indefinite wherein the claim reads “hydrolysis comprises adding one or more organic acids including acetic acid to the alginate...”. It is unclear if applicant intends to add one

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or more acids in addition to acetic acid, or if applicant intends to add one or more acids wherein acetic acid is an option of an acid to choose from.

The term “substantially isolated” in claim 33 is a relative term which renders the claim indefinite. The term “substantially isolated” is not defined by the claim, and one of ordinary skill in the art would not be reasonably appraised of the scope of the invention.

Independent claim 38 is indefinite wherein the claim reads “the isolated polymannuronate”. It is unclear if applicant is referring to another isolated polymannuronate by the recitation of “~~the~~ isolated polymannuronate”. Changing “the” to “an” would obviate the rejection instantly at hand.

Claim 56 is indefinite wherein the claim is drawn to “a method of treatment ... of controlling cholesterol level in blood, controlling serum lipids, ... enhancing functions of liver ...”. It is unclear how one can treat these “controlling and enhancing” functions. One can treat conditions and disorders, but one cannot treat “controlling and enhancing”.

Claim 61 is indefinite wherein the claim reads “expelling heavy metals from a body...”. It is unclear what “a body” is referring to, is it a body of water, a body of a tree, etc.?

Additionally, claim 61 is indefinite wherein the claim is drawn to “a method of expelling heavy metals from a body comprising administering a composition...”, but does not set forth to whom the composition is administered to. Method claims must contain an active step, wherein “administering” is not seen as an active step when there is no recipient of the composition set forth.

All claims which depend from an indefinite claim are also indefinite. *Ex parte Cordova, 10 U.S.P.Q. 2d 1949, 1952 (P.T.O. Bd. App. 1989).*

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-3, 7-9, 12-17, and 19-23 are rejected under 35 U.S.C. 102(e) as being anticipated by Simensen et al. (US Patent 6,121,441), newly cited.

The claims of the instant invention are drawn to a method of preparing a polymannuronate composition comprising hydrolyzing alginate with an organic acid (acetic acid) having a concentration of about 0.2 – 0.6 M and heating, wherein the resulting mixture comprises polymannuronate and polyguluronate and the polymannuronate has a molecular weight in the range of 4,000 to 500,000 Daltons (preferably 40,000 – 50,000 Da). The polymannuronate is then isolated by adjusting the pH to a range from about 2.5 – 3.5 (preferably 2.8 – 3.0) by adding an organic acid thereby forming a precipitate in the mixture, then collecting the supernatant and precipitating the polymannuronate out of the supernatant giving a polymannuronate of about 70% - 98% pure (preferably 90 – 95% pure).

Simensen et al. teach a process of isolating an M block fraction (polymannuronate) from alginic acid comprising the steps of hydrolyzing alginic acid at 40-100°C with an acid which has a concentration in the range of 0.05-5M so that the fraction containing MG blocks dissolves,

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separate MG fraction, adjust the pH to 2.8-4.0 to dissolve the M block, separate the undissolved G block, collect supernatant and produce in pure form a fraction of M block by adjusting the pH to 1.4-0.5 with an acid wherein the M block fraction precipitates out, finally, the M block will be isolated by subsequent filtration or centrifugation steps (column 4, line 40 – column 5, line 11).

Simensen teaches the acids which may be used can be weak acids (column 6, lines 35-43).

Simensen then teach it is preferable to produce a polysaccharide which has a mean molar weight of 1,000-100,000 g/mol, which is seen to overlap with the claimed molecular weight in daltons in the instant application. Simensen et al. also teach it is possible to use algae as the starting material and to use any alginate as raw material (column 7, lines 9-19)

To determine patentability of a “method to make” a material, the patentability of the process must be based on the inventiveness of the **process steps themselves**. See *Ex parte Ochiai (BPAI 1992) 24 PQ2d 1265*. The disclosure of Simensen et al. is seen to anticipate claims 1-3, 7-9, 12-17, and 19-23 of the instant application as the process steps are indeed taught in the prior art.

Claims 24, 26, 29-34 and 36-40 are rejected under 35 U.S.C. 102(e) as being anticipated by Simensen et al. (US Patent 6,121,441), newly cited.

The claims of the instant application are drawn to compositions which comprise polymannuronate with a molecular weight of about 40,000 Da to 80,000 Da which is produced by the process as set forth supra. Dependent claims provide limitations to the properties of the composition which are inherent to the compound in the composition based on the properties of the compounds contained therein, that is the polymannuronate. It is noted that claims 24, 26 and

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29-32 are product by process claims, wherein the process limitations are of no patentable weight.

In re Thorpe, 227 USPQ 964, 966 (Fed Cir 1965).

Simensen et al. disclose a process for preparing a polymannuronate composition with correlative process steps as set forth supra. It is noted that they do not specifically disclose the composition as in the instant applications claims, but one would expect that the correlative process steps would produce a correlative result, thus obtaining the composition as in the instant application. Since the Office does not have the facilities for preparing the claimed materials and comparing them with prior art inventions, the burden is on Applicant to show a novel or unobvious difference between the claimed product and the product of the prior art as they are produced by the correlative process steps. See ***In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977)*** and ***In re Fitzgerald et al., 619 F.2d 67, 205 USPQ 594 (CCPA 1980).***

Claim Rejections - 35 USC § 103

Claims 61 and 62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eliaz et al. for reasons of record.

Claims 61 and 62 are drawn to a method of expelling heavy metals from the body comprising administering a composition comprising polymannuronate or polygluronate and a carrier (to a patient) wherein the molecular weight of the polymannuronate is from about 4,000 Da to 500,000 Da and the metals are selected from Ca, Cd, Cp, Cu, Fe, Hg, Mn, Ru, St, Zn, and Pb.

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Eliaz et al. teach to use low molecular weight alginate of about 40,000 Da or below combined with a carrier to remove heavy metals from the body, such as Ca (column 2, lines 51-65). What is not taught is the use of polymannuronate or polygluronate.

It would have been obvious to one of ordinary skill in the art at the time of the invention to use a composition comprising polymannuronate or polygluronate to remove heavy metals, as it is known in the art that alginate inherently comprises polymannuronate and polygluronate.

Thus, the method of Eliaz et al. teaches the method of the instant application.

Applicants argue that the references, including Eliaz et al., do not teach or suggest the use of a polymannuronate or polygluronate composition to expel heavy metals. However, as set forth supra, a composition of alginate would indeed comprise polymannuronate or polygluronate.

Eliaz et al. teach that alginates are formed by a mixture of polymannuronic acid and polyguluronic acid, thus it would have been obvious to one of ordinary skill in the art to use a composition comprising polymannuronate or polyguluronate to expel heavy metals, as it is known that alginate comprises mixtures of polymannuronate and polyguluronate.

Applicant's arguments with respect to claims 1-3, 7-9, 12-17, 19-24, 26, 29-34 and 36-40 have been considered but are moot in view of the new ground(s) of rejection as set forth supra.

Applicant's arguments drawn to the combination of Eliaz et al. and Dorian et al. in the first office action are centered around the fact that neither teach the use of organic acids, and specifically acetic acid. As set forth supra, Simensen et al. disclose the same reaction steps and direct one to use acetic acid as an acid used in the process of hydrolysis.

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Claims 4-6, 41-48, 50-52, 55-56 and 59-60 appear to be free of the art, as applicant have amended the claims to contain the polymannuronate which has a molecular weight of between 40,000 Da to 80,000 Da. The art does not teach or fairly suggest the specific molecular weight range, which coupled with the declaration showing the beneficial cholesterol binding capabilities in said range, which would direct one to choose this specific range.

Conclusion

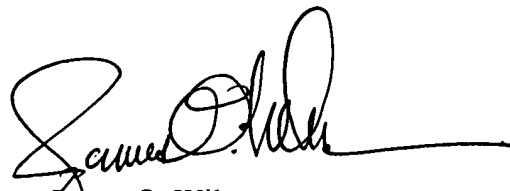
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Traviss C McIntosh whose telephone number is 703-308-9479.

The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 703-308-4624. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Traviss C. McIntosh
May 19, 2003



James O. Wilson
Supervisory Patent Examiner
Art Unit 1623